

Economic Impact Statement

LSA Document #08-412

[IC 4-22-2.1-5](#) Statement Concerning Rules Affecting Small Businesses**Description of the Rule**

The proposed opioid treatment program (OTP) rules are being promulgated as a result of amendments made to [IC 12-23-18](#) in the 2007 session of the Indiana General Assembly. The amendments give the Division of Mental Health and Addiction (DMHA) increased authority in the regulation of Indiana OTPs and establish mechanisms for enforcing compliance with the rules if an OTP does not comply with requirements set forth in the rules. The proposed rules establish the following:

Requirements for the DMHA's specific approval of OTPs and annual certification of opioid treatment facilities.

Requirements for an OTP in the establishment and administration of an OTP diversion control and oversight program to identify individuals who divert opioid treatment medications from legitimate treatment use and to terminate the opioid treatment of those individuals.

Requirements for an OTP to submit a diversion control plan to the DMHA by February 28 each year with the plan to include (1) patient drug testing procedures and (2) requirements for action by an OTP after a patient tests positive for a controlled substance that is not part of the patient's treatment plan or for which the patient lacks a prescription.

The methodology to be used by the DMHA to determine the yearly per-patient fee to be paid by each OTP in Indiana, which fee may not exceed (1) \$75 per patient and (2) the DMHA's costs of implementing and administering the requirements of [IC 12-23-18](#) and [440 IAC 10](#).

Minimum standards for the operation of an OTP in Indiana.

Economic Impact on Small Businesses**1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.**

The provisions of [IC 4-22-2.1-4](#) define a small business as any person, firm, corporation, limited liability company, partnership, or association that:

- (1) Is actively engaged in business in Indiana and maintains its principal place of business in Indiana;
- (2) Is independently owned and operated;
- (3) Employs one hundred (100) or fewer full-time employees; and
- (4) Has gross annual receipts of five million dollars (\$5,000,000) or less.

The DMHA certifies, approves, and regulates 14 OTPs. The DMHA understands that the 14 OTPs can be categorized as follows with regard to their status as a small business under [IC 4-22-2.1-4](#):

Three OTPs are operated by community mental health centers (CMHCs), are publicly funded, and do not meet the definition of a small business.

Five OTPs are owned and operated by one for-profit company and appear not to meet the definition of a small business in [IC 4-22-2.1-4](#).

Six OTPs believe that they meet the definition of a small business under [IC 4-22-2.1-4](#).

All 14 of the OTPs will be subject to the proposed rules.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rules.

The DMHA surveyed four of the six OTPs identifying themselves as small businesses, with capacities ranging from 100 to 500 patients, to obtain estimates of the costs of implementing the provisions of [IC 12-23-18](#). The OTPs will incur the following expenses as a result of the statutory amendment and the administrative rules:

Costs resulting from increased requirements placed on program operations in the following areas:

Collection and reporting of new data points.

Operating seven days a week instead of six days a week.

Increased monitoring visits as a result of a new facility certification.

Other administrative cost increases related to modifying manuals, modifying written procedures, and training staff.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rules.

The total annual economic impact that compliance with the proposed rule will have on the small businesses subject to the rules includes the following, in addition to the costs listed in item 2. above:

The fees paid to the DMHA for each patient treated by the OTP to cover the costs of the DMHA's implementation and administration of [IC 12-23-18](#).

Increased staff-to-patient ratios.

More frequent staff/patient interactions.

The four small businesses that were surveyed reported that the increased cost of complying with the proposed rules ranged from \$63,000 for the smallest OTP (100-patient) to \$390,000 for the largest OTP (500-patient).

Beyond the direct costs of complying with the proposed rules estimated in item 2 and this item, the OTP small businesses could experience an economic impact if OTP enrollments decline as a result of either treatment cost increases or increased demands on patients to comply with more restrictive program rules or a combination of both. If patients encounter treatment cost increases, they may seek treatment in an adjacent state if convenient and if travel time would be reduced. This option applies especially to the large number of out-of-state patients seeking treatment at Indiana OTPs from the states bordering Indiana. However, it is understood that treatment capacity is limited in both Kentucky and Ohio and is limited to a certain extent in both Illinois and Michigan.

OTP treatment is designed to provide services to individuals who have become addicted to opioid drugs. Treating opioid addiction requires not only medication, but intense interaction with program staff as the individual adjusts to many lifestyle changes. As a result, OTP treatment is demanding and requires that patients come to the OTP daily for an extended period until the patient has demonstrated trustworthiness in handling self-administered medication. Indiana's increased requirements in restricting unsupervised doses for patients who test positive for any illicit drug could discourage patients from entering treatment or give them incentives to seek treatment in other states. Either of these options could result in an economic impact to Indiana small business OTPs.

Furthermore, requiring OTPs to be open seven days a week may discourage some individuals from seeking or remaining in treatment due to a lack of public transportation in some geographic areas and the rising costs of gasoline.

Lastly, opioid addiction treatment is also available from private practicing physicians who have received certification from the federal government. This private treatment does not require counseling, have restrictions on self-administered medication, or require the provider to pay fees to the DMHA based on the number of patients treated.

Patients may encounter increased costs for OTP treatment or may not want to comply with the increased treatment demands required by the OTPs in the form of (1) longer duration until unsupervised doses of medication are permitted; (2) increased counseling; and (3) increased drug testing. As a result, patients may choose to seek treatment from sources other than an Indiana OTP. A potential decline in patient population is, therefore, another possible economic impact on the OTPs.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rules and not expressly required by the statute authorizing the agency to adopt the rules, or any other statute or any other state or federal law.

The rules do not impose requirements or costs that are not expressly required by [IC 12-23-18](#).

5. Regulatory Flexibility Analysis.

A. Establishment of less stringent compliance or reporting requirements for small businesses.

The intent of the statute is to regulate all OTPs in Indiana. While six of the 14 OTPs in Indiana may meet the definition of a small business, the DMHA does not believe it would be appropriate to lessen the requirements on these six OTPs. Because the proposed rules relate in large part to health care matters, it would be difficult to reduce the requirements on small businesses due to the potential impact to the health and safety of patients and OTP employees.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

The 2008 amendments to [IC 12-23-18](#) became effective on July 1, 2008. The proposed rules, which provide standards for operation of OTPs, will not be effective until early Calendar Year 2009. For this reason, establishment of less stringent schedules or deadlines for small businesses is not considered to be indicated.

Reporting requirements under the proposed rules are requirements also of the accreditation agencies of the OTPs and the two federal agencies that regulate the OTPs. Accordingly, the reporting requirements of the rules cannot properly be made less stringent than already contained in the rules.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

The size of the small business OTPs does not place them at a disadvantage for complying with the provisions of the proposed rules. Thus, it is not believed to be appropriate to consider the consolidation or simplification of compliance or reporting requirements for these OTPs.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rules.

The explicit intent of the statute is to regulate all OTPs in Indiana. For this reason, it does not appear to be

appropriate to consider establishment of performance standards for small businesses other than the operational standards established by the rules.

E. Exemptions of small businesses from part or all of the requirements or costs imposed by the rules.

The intent of the statute is to regulate all OTPs in Indiana. For this reason, it is not considered appropriate to exempt small businesses from part or all of the requirements or costs imposed by the proposed rules.

Posted: 11/26/2008 by Legislative Services Agency

An [html](#) version of this document.